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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,597	10/30/2003	Ruxandra Draghia-Akli	AVSI-0027 (108328.00161)	7762
7/0225 7/590 07/14/2009 JACKSON WALKER LLP 901 MAIN STREET SUITE 6000 DALLAS, TX 75202				
EXAMINER MARVICH, MARIA				
ART UNIT		PAPER NUMBER		
1633				
MAIL DATE		DELIVERY MODE		
07/14/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/699,597

Applicant(s)

DRAGHIA-AKLI ET AL.

Examiner

MARIA B. MARVICH

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-31, 39 and 42 is/are pending in the application.
- 4a) Of the above claim(s) 29-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39 and 42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to an amendment filed 3/31/09. Claims 29-31, 39 and 42 are pending in this office action.

Election/Restrictions

Until the product is deemed allowable, search and examination of the process claims with the product imposes an undue burden on the Office. If the product claim is found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. At this time, the product claim has not been found allowable.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Specifically, pages figures 12-19 each comprise two sequences that are not identified by SEQ ID NO:. If the sequences can be found in the sequence listing it would be remedial to insert the appropriate SEQ ID NO:s. If not, a substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, CRF and letter stating that the contents of the sequence listing and the CRF are the same and contain no new matter is required. **The**

nature of the non-compliance did not preclude the examination on the merits of the instant application, the results of which follow.

Response to Amendment

Applicants have amended the description of drawings to insert a single SEQ ID NO: to describe each of the figures. However, there are two sequences in each figure that are not the same as one another. Therefore, a second SEQ ID NO: is required for each figure.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This

Claims 39 is drawn to a cardiac specific-synthetic promoter comprising:

(a) a synthetic promoter element comprising c5-12 (SeqID#5) and further comprising at least one (b) cis-acting regulatory element comprising SRE (SeqID#1); MEF-1 (SeqID#2); MEF-2 (SeqID#3); or TEF-1 (SeqID#4). SEQ ID NO:5 which comprises all of cis-acting regulatory

element comprising SRE (SeqID#1); MEF-1 (SeqID#2); MEF-2 (SeqID#3); and TEF-1 (SeqID#4) as set forth below.

While c5-12 is set forth as

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c5-12
ggcagtcgga cttctgggacg cctctcagc SRE-P cacccaaaac tgggtgttttt TEF-1 50
cctgggagcag MEF-2 cctctcagc MEF-1 MEF-2
cctgggagcag cctctcagc cctgggagc cctctcagc cctgggagc cctctcagc 120
P cctgggagc cctctcagc MEF-2 cctgggagc cctctcagc TEF-1
cctgggagc cctctcagc cctgggagc cctctcagc cctgggagc cctctcagc 180
cctgggagc cctctcagc cctgggagc cctctcagc cctgggagc cctctcagc
cctgggagc cctctcagc cctgggagc cctctcagc cctgggagc cctctcagc 240
cctgggagc cctctcagc cctgggagc cctctcagc cctgggagc cctctcagc
cctgggagc cctctcagc cctgggagc cctctcagc cctgggagc cctctcagc 300
cctgggagc cctctcagc cctgggagc cctctcagc cctgggagc cctctcagc 334
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Hence, claim 39 as recited is drawn to a modification of SEQ ID NO:5 in which additional elements are added. But the specification does not disclose such a promoter. Hence, claim 39 is not supported by the disclosure and constitutes impermissible NEW MATTER.

Response to Amendment

Applicants response filed 3/31/09 has been considered but is ineffective in overcoming the rejection under 35 USC 112, first paragraph. Applicants arguments appear directed at a claim drawn to SEQ ID NO:5 wherein SEQ ID NO:5 comprises at least one of SEQ ID NO:s 1-4. However, the claim is drawn to SEQ ID NO:5 *further* comprising at least one of SEQ ID

NO:s 1-4. The specification teaches that c5-12 is SEQ ID NO:5. The specification does not teach modifications of this sequence.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al (US 5,298,422; see entire document). **This is a new rejection necessitated by applicants' amendment. The instant claim recites that the promoter has "a" sequence as set forth in SEQ ID NO:5. This rejection is directed towards a reading of the claims of a single dinucleotide from SEQ ID NO:5.**

Schwartz et al teach a myogenic vector for expression of a sequence in myogenic tissue (cardiac tissue) using a cardiac specific synthetic promoter (see e.g. figure 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Draghia-Akli et

al (US 7,241,744; see entire document). **This is a new rejection necessitated by applicants' amendment. This rejection is directed towards a reading of the claims of the sequence of SEQ ID NO:5. The rejection has been clarified to reflect that the sequence shown below is SEQ ID NO:16.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Applicants claim a cardiac specific promoter comprising SEQ ID NO:5.

Draghia-Akli et al teach a promoter (SEQ ID NO:16) and furthermore this promoter is 99.7% identical to SEQ ID NO:5. The difference between the two is the first nucleotide which is missing from 10/315907. However, according to the diagram of SEQ ID NO:5, this nucleotide does not perform a critical function nor does it function in the capacity of the promoter. KSR forecloses the argument that a specific teaching, suggestion or motivation is required to support a finding of obviousness. See the recent Board decision *Exparte Smith* --USPD2d--, slip op. at 20, (BD. Pat. App. & Interfer. June 25, 2007). As well, it is within the ordinary skill of the art to use available methodologies to isolate a variety of promoters with C-terminal or N-terminal sequences removed that do not affect the function of the promoter. One would have been motivated to do so in order as the ability to modify sequences by applying conventional

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US-10-315-907C-16
; Sequence 16, Application US/10315907C
; Patent No. 7241744
; GENERAL INFORMATION:
; APPLICANT: Advisys
; TITLE OF INVENTION: PLASMID MEDIATED SUPPLEMENTATION FOR TREATING
CHRONICALLY ILL SUBJECTS
; FILE REFERENCE: 108328.00073 - AVSI-0007
; CURRENT APPLICATION NUMBER: US/10/315,907C
; CURRENT FILING DATE: 2002-12-10
; NUMBER OF SEQ ID NOS: 25
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 16
; LENGTH: 4260
; TYPE: DNA
; ORGANISM: Artificial sequence
; FEATURE:
; OTHER INFORMATION: Sequence for the pSP-SEAP cDNA construct
; Patent No. 7241744
US-10-315-907C-16

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Query Match          99.7%; Score 334; DB 5; Length 4260;
Best Local Similarity 100.0%; Pred. No. 1.8e-83;
Matches 334; Conservative 0; Mismatches 0; Indels 0; Gaps
0;

Qy          2  GGCCGTCGCGCTTCGGCACCATCCTCAGCACACCCAAATATGGCGACGGGTGAGGAATGG 61
           |||
Db          1  GGCCGTCGCGCTTCGGCACCATCCTCAGCACACCCAAATATGGCGACGGGTGAGGAATGG 60

Qy          62  TGGGGAGTTATTTTATAGCGGTGAGGAAGGTGGGCAGGCAGCAGGTGTTGGCGCTCTAA
121          |||

Db          61  TGGGGAGTTATTTTATAGCGGTGAGGAAGGTGGGCAGGCAGCAGGTGTTGGCGCTCTAA
120          |||

Qy          122  AAATAACTCCCGGAGTTATTTTATAGCGGAGGAATGGTGGACACCCAAATATGGCGAC
181          |||

Db          121  AAATAACTCCCGGAGTTATTTTATAGCGGAGGAATGGTGGACACCCAAATATGGCGAC
180          |||

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Qy      182  GGTTCCTCACCCGTCGCCATATTTGGGTGTCCGCCCTCGGCCGGGGCCGCATTCTGGGG
241      |
Db      181  GGTTCCTCACCCGTCGCCATATTTGGGTGTCCGCCCTCGGCCGGGGCCGCATTCTGGGG
240      |
Qy      242  GCCGGGCGGTGCTCCGCCCGCCTCGATAAAAGGCTCCGGGCCGGCGGGCGGCCACGAG
301      |
Db      241  GCCGGGCGGTGCTCCGCCCGCCTCGATAAAAGGCTCCGGGCCGGCGGGCGGCCACGAG
300      |
Qy      302  CTACCCGGAGGAGCGGGAGGCGCCAAGCTCTAGA  335
Db      301  CTACCCGGAGGAGCGGGAGGCGCCAAGCTCTAGA  334

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Response to Amendment

Applicants response filed 3/31/09 has been considered but is ineffective in overcoming the rejection under 35 USC 102 and 103. Applicants have argued that neither SEQ ID NO:1 nor 7 of Draghia-Akli et al matches that of SEQ ID NO:5. However, as set forth in the body of the rejection, a match of 99.7% of SEQ ID NO:16 and SEQ IDNO:5 have been identified. While the sequences was incorrectly listed in the body of the rejection as SEQ ID NO:1, it was correctly set forth in the sequence comparison. This sequence number identifier is bolded in the computer generated sequence alignment.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Weitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Primary Examiner
Art Unit 1633

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/Maria B Marvich/
Primary Examiner, Art Unit 1633